

## **Physiotherapist-led exercise classes for low back pain show changes in disability and fear of movement: a service evaluation**

MackKelvie, Claire P.; Seenan, Chris; Ryan, Cormac G.

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**Title:** Physiotherapist-led Exercise Classes for Low Back Pain Show Changes in Disability and Fear of Movement: A service evaluation.

**Disclosures:**

The corresponding author is employed by Greater Glasgow and Clyde (GGC) health board from which the data sample was taken. The authors declare that they have no conflicts of interest in the authorship and publication of this review.

**Consent and Data Protection:** All participants consented to use of their outcome measures for audit and/or research at point of referral to a class. The same outcome measures were being used in the classes before the evaluation period started, so no further approval was required. All patient identifiable information was removed and/or anonymised before analysis. The researcher was already based as a clinician within the health board.

## **Abstract:**

**Objective:** This evaluation aimed to examine the effects of physiotherapist-led back classes in a health care setting on measures of disability and pain-related fear of movement.

**Design:** A service evaluation of pre- and post-class outcome measures with additional follow-up at 6 months and 1 year.

**Participants:** 447 participants (299 women) with low back pain [LBP] (with or without leg pain).

**Interventions:** Six sessions, one hour per week, of 'Back to Fitness' physiotherapist-led exercise classes for LBP based on a biopsychosocial approach.

**Outcome Measures:** Roland Morris Disability Questionnaire (RMDQ) and the Tampa Scale of Kinesiophobia 13 (TSK-13).

**Results:** Of the 447 participants, 210 participants completed baseline and week 6 outcome measures (47%). 218 were sent 6 month follow up questionnaires and 59 responded (27%). The 59 responders from the 6 month follow up were sent 1 year follow up questionnaires to which 21 responded (36%). Significant and clinically relevant reductions in RMDQ were seen immediately post class. Further reductions were seen at 6 months and 12 months with a 50% [2.3 points,  $p < 0.05$ ] reduction in mean RMDQ score at 1 year. TSK-13 scores significantly reduced in a similar pattern though the results at one year were not statistically significant.

**Conclusions:** 'Back to Fitness' physiotherapist-led exercise classes can reduce disability and pain-related fear of movement in patients with LBP. Reductions in disability were maintained for up to one year. Given the non-controlled nature of this evaluation we cannot attribute cause and effect. The large dropout rate also warrants

caution when interpreting these results. However, these findings suggest that the effects of group exercise classes reported in the literature can be reasonably generalised to the modern day real world NHS setting.

**Keywords:**

Low back pain - Physiotherapy - Disability - Back Class - Service Evaluation - NHS

## **1. Background**

Low back pain (LBP) is the number one cause of disability worldwide <sup>1</sup> and it constitutes a considerable economic burden in the UK <sup>1,2,3</sup>. Many trials have looked at the effectiveness of different treatments. Exercise therapy, especially in a group setting or as part of a 'Back School', has been widely recommended for the management of sub-acute and chronic LBP, with or without leg pain <sup>3-6</sup>. UK trials have demonstrated the long-term benefits of group-based aerobic exercise classes, such as the 'Back to Fitness' programme designed to help patients to regain confidence in moving normally <sup>7-9</sup>. Such exercise classes have been shown to be a cost-effective option compared with one-to-one usual care physiotherapy <sup>7, 8</sup>. A more recent systematic review of exercise classes for LBP found them more effective for pain and function than other conservative treatments <sup>4</sup> and group exercise classes are recommended by National Institute for Health and Care Excellence (NICE) <sup>10</sup>. In addition, chronic LBP guidelines consistently recommend supervised therapeutic exercise / physical activity for management of the condition <sup>11</sup>.

While the evidence is promising it remains incomplete and large scale studies with high numbers of patients are required to further explore the role of exercise therapies in LBP <sup>6, 12</sup>. Moreover, despite a good level of agreement within the literature that exercise classes appear beneficial, there exists a lack of real-world patient data to support the use of these classes within the National Health Service (NHS) setting. Such data is important to establish if the results achieved under the tightly controlled conditions of a clinical trial generalise to the variable everyday realities of clinical practice.

Greater Glasgow and Clyde (GGC) Health Board has provided physiotherapist-led back classes for at least 14 years within primary care musculoskeletal services. The GGC Back Pain Service is underpinned by a biopsychosocial approach to pain management and the back classes broadly follow the reactivation approach similar to the 'Back to Fitness' structure <sup>7, 9</sup>. To date the service has not been formally evaluated. Thus, the aim of this study was to evaluate the effectiveness of the GGC physiotherapist-led back classes for patients with LBP.

## **2. Methodology**

### **2.1 Study Design**

This was an evaluation of adults over the age of 18 in primary care with any duration of LBP, with or without leg pain, who had been referred to a physiotherapist-led back class in GGC. Nine sites that were running back classes within GGC were included. 465 patients had started, or were due to start, a class between the dates of 1<sup>st</sup> October

2012 and 30<sup>th</sup> September 2013. Participants were aged between 18-80 years with only 8% over 65.

## 2.2 Recruitment

The inclusion and exclusion criteria for referral to the back classes are detailed in Table 1. Musculoskeletal physiotherapists in GGC referred patients with LBP to the back classes. All physiotherapist referrers conducted a full lumbar assessment of the patient prior to referral to a class and would have administered usual physiotherapy care including advice, educational information and treatment(s). They were encouraged to view the back classes as an early supported exit route for their patients. All referring physiotherapists had access to the referral guidelines which included exclusion and inclusion criteria for the GGC back classes. In addition all referrals were screened by back class staff and not accepted into the class if deemed inappropriate against the inclusion/exclusion criteria.

Inclusion Criteria	Exclusion Criteria
1) Acute, sub-acute, episodic or chronic Low Back Pain of benign origin (consider exercise tolerance / severity / irritability) 2) Patients must be motivated (consider stage of change), able and willing to participate in a mixed group of low to moderate level exercise. 3) Appropriate Musculoskeletal assessment, with advice on self management and education. 4) Patients must be able to understand written and spoken English	1) Unstable cardiovascular system, respiratory system or any medical condition that is unstable 2) Red flags, considered clinically significant 3) Persistent, severe Low Back Pain with nerve root involvement or unstable neurology 4) High severity/irritability/distress levels 5) Spinal surgery within 6 weeks 6) Recent spinal fracture <3 months 7) Pregnancy or <3 months post-partum 8) Systemic inflammatory disease (during an acute episode) 9) Course of radiotherapy within 3 months 10) Severely disabled (unable to get on and off the floor unaided)

**Table 1.** Inclusion and exclusion criteria for the Back Classes

## 2.3 Class Content

In the year prior to data collection, GGC class access, structure and content was reviewed and standardised across all nine sites as far as possible so as to be achievable even if limited space or equipment was available. Resources and training for class leaders were put in place, with regular meetings and reflection on practice. Training and updates for leaders occur annually including topics such as class-taking skills and behaviour change and update on links to community exercise services. A central electronic location for data input for all back classes was developed and outcome measures introduced so that audit and evaluation would be facilitated.

The classes were designed around a general reactivation programme<sup>7-9</sup>. They were promoted as a springboard to help participants get back to normal activities and / or independent community exercise but with clinical supervision and a mutually supportive environment. The back classes were based on biopsychosocial principles and were 1 hour per week for 6 weeks. All classes adhered to an agreed class format of general aerobic activity, functional exercises, stretching, strengthening and cool down with relaxation. Each class included a 10 minute gentle aerobic warm up as a whole group followed by a variety of circuits or stations, with graded options, for about 30 minutes. Classes contained 5-10 circuits and included a variety of exercises e.g. marching, side steps, mini squats, cycling, shuttle-walks, marching on trampet, sit to stand, step ups, wall press, and pelvic tilts. Other alternative activities were chosen by class leaders depending on equipment availability but they would be in keeping with a low to moderate level stretching, strengthening or aerobic activity.

In each class across GGC a flexion-based 'functional station' circuit was common to all classes: This circuit would be either lumbar flexion in sitting, or lumbar flexion in

standing, depending on which of these two functional movements was deemed more of a priority by the patient and/or physiotherapist. This station was described to participants as the area where they could work on specific flexibility to be able to dress more easily or to be able to reach the floor more easily when standing, so that they could see the relevance of the circuit. Following the circuits, each class had a mat work section including strengthening exercises for abdominal and hip muscles and stretches including pelvic tilting in 4-point kneeling, bridging and lumbar rotation in lying and then 5-10 minutes of relaxation to finish.

All participants were given relevant verbal information about back health and general health. In addition, positive health exercise messages were delivered during the classes, for example ‘hurts won’t harm’, ‘motion is lotion’, and ‘a little pain is ok, but work at a level comfortable for you’. Posters were placed around the gym with inspirational statements or quotes such as ‘there is no such thing as bad weather, only the wrong clothing’. They were encouraged to exercise within their own limits of comfort but not to let pain be their guide, and encouraged to do a little more each week if they could. During the final session(s) patients were sign-posted towards continued independent exercise in the community and supplied with relevant, individualised contact information as appropriate. Further follow-up to assess compliance or uptake of independent exercise in the community was not undertaken.

## 2.4 Outcome Measures

The outcomes measures used were the Roland-Morris Disability Questionnaire (RMDQ) and the Tampa Scale of Kinesiphobia-13 (TSK-13). These are both reliable and validated self-reported outcome measures<sup>13,14,15</sup>.



Signed patient consent was obtained at referral stage and participants who did not consent to their data being used for evaluation purposes were excluded from the data analysis. On week 1 and prior to the first class beginning all participants completed baseline RMDQ and TSK-13. The same two questionnaires were completed by patients who attended the final class on week 6. At 6 months post intervention patients who had attended 5 or more of the classes were sent the same two follow up questionnaires. Finally, the participants who responded to the 6 months questionnaires were sent the same two questionnaires again at 1 year follow-up.

### **Roland-Morris Disability Questionnaire**

The RMDQ is a widely recognised, reliable, and valid measure of physical disability for patients with LBP. It is a frequently used measure of activity limitation in LBP research. The scale is 0-24, where 24 is maximum disability and 0 is no disability. A difference of 2-3 points on the RMDQ is considered to be a clinically relevant difference by the original authors<sup>13</sup>. Stratford et al, as cited by Roland and Fairbank<sup>13</sup>, looked at minimum clinically important changes in the RMDQ and suggested that 1-2 point change was clinically important in groups with low pre-intervention disability (0-11) and that 7-8 points was an important change in groups with high pre-intervention disability (12-24).

### **Tampa Scale of Kinesiphobia-13**

The TSK-13 is a valid and reliable measure of pain-related fear of movement, also known as kinesiophobia. A recent meta-analysis of pain related fear and disability in 2013<sup>14</sup>, found that pain related fear is positively related to disability. The TSK-13 is a

modified version of the original 17 item TSK. The TSK-13 is scored from 13-52 where 13 is the lowest amount of kinesiophobia and 52 the highest. Few studies have discussed significant or clinically relevant differences in scores for the TSK-13. Neblett et al <sup>15</sup> suggested that severity groupings of ‘subclinical’ (13-22), ‘mild’ (23-32), ‘moderate’ (33-42) and ‘severe’ (43-52) could be applied to scores from the TSK-13.

## 2.5 Data Analysis

Participant characteristics are presented using simple descriptive statistics.

We assessed for normal distribution using the Shapiro-Wilk test. The TSK-13 and RMDQ scores were normally distributed and therefore simple paired t-tests were conducted. T-tests were used to analyse the data, comparing baseline to week 6, baseline to 6 months and baseline to 12 months. Differences in outcomes across the nine individual sites were also explored.

As well as the clinical outcome measures the number of patients who completed the classes, the numbers who failed to attend and the number of drop outs were recorded. The authors defined completers, failed to attends, drop-out and non-responders as follows:

- Completers: defined as having attended the last agreed planned session, even if they had missed one or more classes.
- Failed to attend: defined as people who did not attend any classes at all.
- Drop out: defined as those who missed the last agreed session and therefore did not complete immediate post class (week 6) outcome measures.

- Non-responders: people who did not return postal questionnaires at 6 months follow up.

### 3. Results

#### 3.1 Patient demographics and response rates

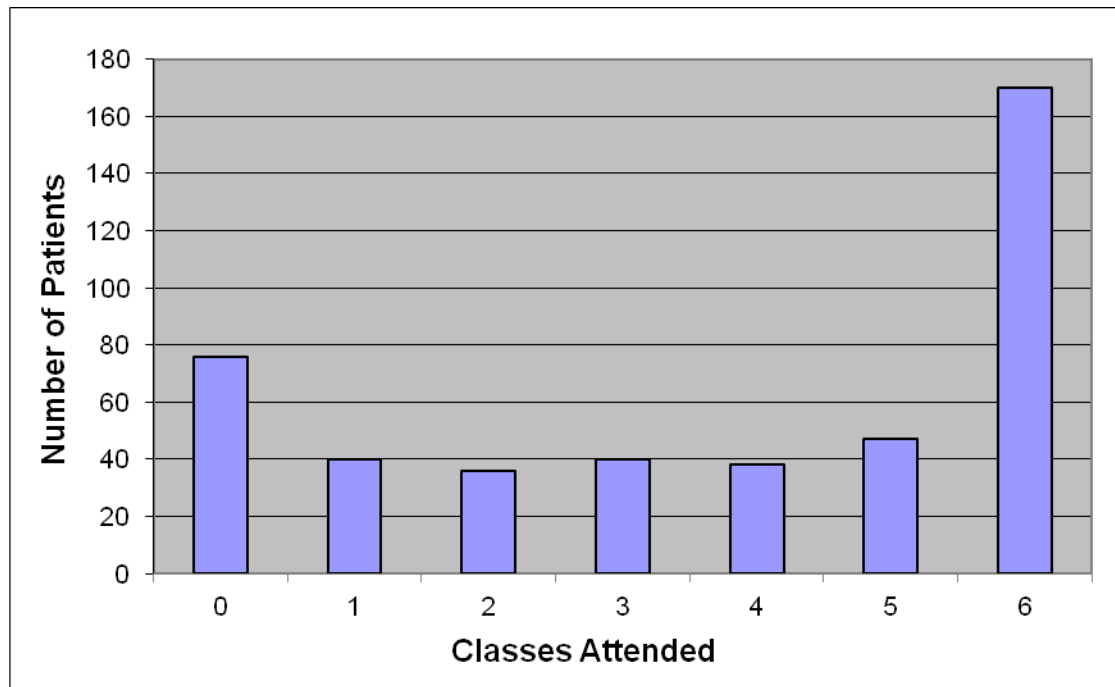
465 patients were invited to start the back exercise classes between 1<sup>st</sup> October 2012 and 30<sup>th</sup> September 2013. 18 were excluded from data analysis due to non-consent (n=16) or incomplete data (n=2). 447 participants (female n =299, male n = 148) with LBP were included in the analysis:

- 210 participants completed baseline and week 6 outcome measures (47%).
- 218 were sent 6 month follow up questionnaires and 59 responded (27%).
- The 59 responders were also sent 1 year follow up questionnaires with 21 responders (36%).

#### 3.2 Compliance

76 patients failed to attend the classes (16.3% of referrals) and were therefore discharged from physiotherapy services with no follow-up. 227 people (50.8%) completed the classes. 210 (47%) completed baseline and week 6 outcome measures. Figure 1 shows overall attendance at classes. Dropout rate in the current study (49.2%) was noted as being somewhat higher than in similar studies <sup>7</sup>.

Figure 1: Number of classes attended by participants



### RMDQ

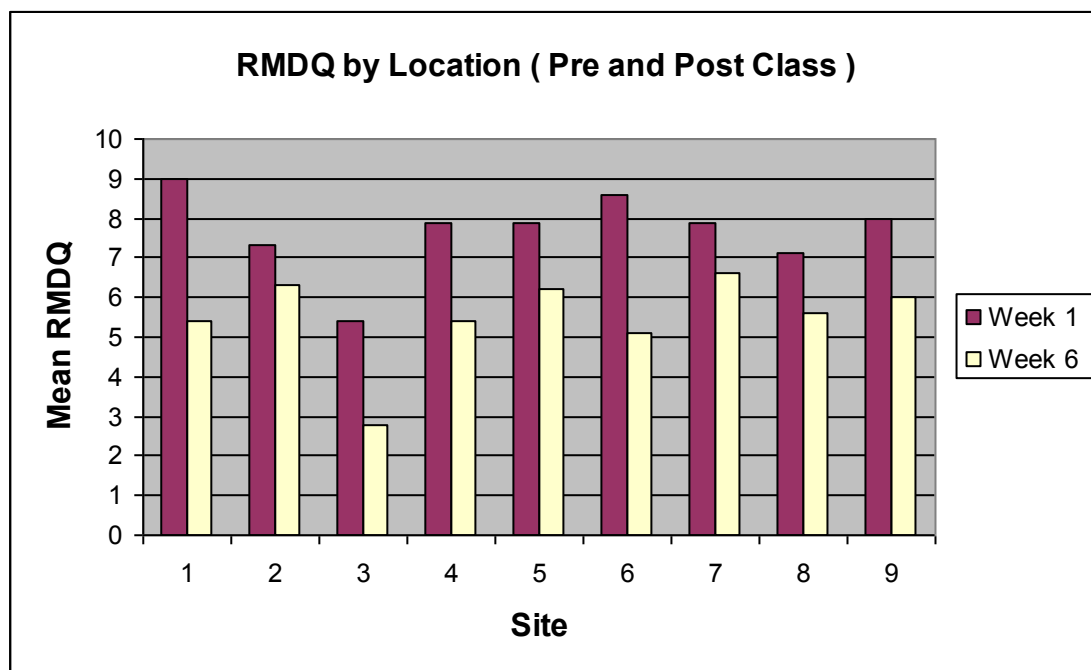
Significant and clinically relevant reductions in RMDQ scores were found

immediately post class (Mean change = -1.9 (SD 3.8),  $t(209) = 7.13, p < .001$ ).

Further reductions were seen at 6 months (Mean Change = - 1.88 (SD 3.88),  $t(58) = 3.72, p < 0.001$ ). At 12 months there was a 50% reduction in mean RMDQ score compared to baseline (Mean change = -2.29 (SD 4.19),  $t(20) = 2.50, p < .05$ ).

Figure 2 shows the mean RMDQ scores before and after the six exercise classes at each class site from Week 1 (baseline) to Week 6 and shows that some sites had higher mean RMDQ at baseline than others. Figure 2 also indicates that sites with higher baseline disability levels made larger magnitude improvements.

Figure 2. RMDQ by class location Week 1 (pre-class) to Week 6 (post-class).



*Legend: RMDQ Roland Morris Disability Questionnaire.*

### TSK-13

Scores on the TSK-13 decreased from baseline to post class (Mean change = -3.41 (SD 6.07),  $t(210) = 8.17$ ,  $p < .001$ ) and at 6 months (Mean change = -2.22 (SD 5.64),  $t(58) = 3.03$ ,  $p < .01$ ). At 1 year follow-up mean TSK-13 scores also decreased although this was not statistically significant (Mean change = -3.29 (SD 8.18),  $t(20) = 1.84$ ,  $p < 0.1$ ).

## **4. Discussion**

The aim of this service evaluation was to evaluate the effectiveness of physiotherapist-led group exercise classes for fear of movement and functional disability in patients with LBP with or without leg pain. In the short and longer term, patients with LBP with or without leg pain who participated in a 1 hour physiotherapist-led graded activity exercise class for five or six sessions were found to have significantly lower levels of functional disability and fear of movement.

Moreover, in accordance with the literature<sup>13, 14, 15</sup>, patients who started a class with higher levels of functional disability or moderate to high pain related fear of movement made larger magnitude improvements in both.

Improvements in the RMDQ may have been only approaching clinically relevant changes from baseline to week 6, but encouragingly they showed clear clinically important improvements at 6 months and one year after the classes with 50% reduction in RMDQ scores seen at 1 year. These findings are in keeping with previous clinical trial findings (mean change RMDQ -2.86 at 6 weeks and -3.19 at 1 year)<sup>7</sup> and imply that such findings are generalisable into the real world NHS setting.

Reductions in pain-related fear of movement showed clinically important improvements immediately post class (week 6) and although there was some tailing off at 6 months the size of improvements increased again at 1 year after the classes and were clinically encouraging even if the findings at 1 year were not statistically significant. It is plausible that this lack of statistical significance was related to the small sample size at this point. Again, these real-life data findings add weight to the literature and demonstrate the generalisability of previous trial findings to the NHS.

A systematic review of 61 trials of exercise therapy for the treatment of low back pain found that exercise is effective at reducing pain and improving function, particularly in a health care setting<sup>4</sup>. The current study, also relating to exercise in a health care setting, echoes this benefit. Physiotherapists in a health care setting seeking evidence-based interventions for patients with LBP with or without leg pain should consider group exercise interventions as a compelling option.

The ideal type and duration of exercise in group exercise programmes for LBP remains contentious; Van Tulder et al <sup>4</sup> in their systematic review of exercise therapy identified that the heterogeneity of exercise interventions offered in the RCT's was a limitation. Therefore evidence is lacking for any one kind of specific back exercise regime but research seems to point more towards general active rehabilitation, with a functional focus and behavioural change components <sup>3</sup>. The authors believe the intervention studied here is aligned more with such an approach than exclusively exercise therapy.

### **5. Implications for Clinical Practice**

Given the long-term clinically relevant beneficial effects on disability and pain related fear shown in this evaluation, coupled with the relatively low cost of the exercise-classes, these classes would appear to be an appropriate use of NHS clinical resources in the management of LBP.

### **6. Limitations**

In respect to generalisability, a strength of this study is that it has been undertaken in a real life setting across multiple sites and therefore can be reasonably generalised to a the wider NHS in the United Kingdom. However, there was no control group or blinding of any kind, As such any improvements seen in patients cannot be definitively attributed to the intervention and could have been the consequence of improvement over time, regression to the mean, placebo effects or some other non-specific effects. Additionally, the outcomes reported are only targeted at those who

completed the classes. Due to lack of resources a clinical decision was made, in part based on other similar trials of classes <sup>4,7</sup> to only follow up people who had completed 5 or 6 classes. It would have been useful to look at outcomes from poor compliers and non-responders at 6 months but this was not possible given our limited resources. It is difficult to speculate the reasons behind non-responses but suggested reasons may be lack of meaning to the patient, time constraints, lack of perceived importance or feelings of irrelevance due to improvements. Another limitation of this work is that we did not record duration of participant's symptoms and so it is unclear how these findings relate to patients with acute pain or chronic pain.

There was a relatively high drop out from the classes compared with similar studies <sup>7</sup> which identified that the classes may not be appropriate for all patients with LBP for a variety of reasons. It would have been interesting to have analysed the data accounting for missing data using a technique such as last data point carried forward. However, given the considerably high dropout numbers such an analysis was inappropriate and potentially misleading. It should be noted that the reporting of findings where drop outs ignored in the analysis, as we have done here, are likely to over-inflate the apparent effectiveness of the intervention. A key direction for future work would be to explore the reasons for the relatively high proportion of drop outs and identify ways to reduce them.

## **7. Conclusions:**

A six-week 'Back to Fitness' graded, functional exercise programme in an NHS, health care setting produced clinically relevant improvements in RMDQ and TSK-13 scores in patients with LBP with or without leg pain. The improvements appear to



extend to the longer term. Targeting patients with moderate to high disability and fear levels may produce the greatest effects. These findings show that the results of clinical trials of exercise therapy for LBP can broadly be generalised into the modern day NHS. These results should be interpreted cautiously due to the large drop-out rates and therefore relatively low sample size on follow-up. Future work should focus on the high number of drop-outs from these classes, explore why they occur and consider how they can be reduced.

## **8. Acknowledgments**

The authors would like to thank all back class staff for their tireless work and GGC Musculoskeletal physiotherapy managers for their support of the work. The authors have no conflicts of interest to declare and this evaluation received no funding support.

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